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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,242	04/02/2001	Stephen Eisenberg	019496-001810US	2688
20350	7590	07/02/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP			BRUSCA, JOHN S	
TWO EMBARCADERO CENTER			ART UNIT	
EIGHTH FLOOR			PAPER NUMBER	
SAN FRANCISCO, CA 94111-3834			1631	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,242

Applicant(s)

EISENBERG ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35,37-43,48,49,52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35,37-43,48,49,52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03 June 2004 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 35, 37-43, 48, 49, and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35, 37-43, 48, 49, and 52 are indefinite for recitation of the phrase "a new zinc finger protein" because the metes and bounds of the phrase are not clear. In particular it is not clear at what time or to whom the protein is new. The rejection would be overcome by deletion of the term "new" from the claims.

Claim 39 is indefinite because the claim requires each subset in the method to be a null set, while claim 37 from which it indirectly depends requires each subset to comprise zinc finger proteins.

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4. For the purpose of examination, the claims have been assumed to incorporate the suggested amendments.

Claim Rejections - 35 USC § 102

5. The rejection of claims 35, 37-40, 42, 43, and 53 under 35 U.S.C. 102(b) as being anticipated by Desjarlais et al. is withdrawn in view of the amendment filed 15 March 2004 amending claims 35, 37-40, 42, and 43 to recite the limitation "a database comprising designations for a plurality of precharacterized zinc finger proteins." Desjarlais et al. does not show in figure 1 precharacterized zinc finger proteins because figure 1 shows the zinc finger proteins designed by Desjarlais et al. In addition, Desjarlais does not show the computer mediated method of claim 53.

Claim Rejections - 35 USC § 103

6. The rejection of claims 48 and 49 under 35 U.S.C. 103(a) as being unpatentable over Desjarlais et al. is withdrawn in view of the amendment filed 15 March 2004 amending claims 48 and 49 to recite the limitation "a database comprising designations for a plurality of precharacterized zinc finger proteins." Desjarlais et al. does not show in figure 1 precharacterized zinc finger proteins because figure 1 shows the zinc finger proteins designed by Desjarlais et al.
7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Desjarlais et al.

The claim is drawn to a computer implemented method of designing a zinc finger protein comprising three zinc fingers by using a database that comprises a plurality of zinc finger protein sequences in which the zinc finger domains are correlated with their respective DNA binding target.

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Desjarlais et al. shows a database in figure 1 that comprises two zinc finger protein sequences and correlates each of the three zinc finger domains with a DNA binding target. Desjarlais et al. shows in figures 3 and 4 that after synthesis, the zinc finger proteins bind to their expected DNA target. Desjarlais et al. does not show computers and programs that assemble and utilize their database.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to automate the generation and use of their database because it is obvious to one of ordinary skill in the art to automate a process (see MPEP 2144.04).

11. Applicant's arguments filed 15 March 2004 have been fully considered but they are not persuasive. The applicants state that Desjarlais does not show a computer implemented method and that the rejection of claim 53 under 35 U.S.C. § 102(b) in the Office action mailed 29 January 2004 is improper. The applicant's arguments are persuasive in that regard and the rejection of claim 53 under 35 U.S.C. § 102(b) has been withdrawn as noted above, however a new rejection of claim 53 under 35 U.S.C. § 103(a) over Desjarlais et al. has been made above. The applicants further state in their arguments filed 15 March 2004 that Desjarlais et al. does not make obvious claims drawn to programs or computers that execute the claimed method. The applicants state that Desjarlais et al. only shows two proteins in the database of figure 1 which does not lead to advantages in automation. Because it is convenient to store any database, however small, in computer memory, it would nevertheless be obvious to use a computer in the claimed method of claim 53.

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12. Claims 35, 37, 38, 40, 42, 43, 48, 49, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choo et al. (1994b) (Nature Vol 372, pages 642-645, reference DB in the information disclosure statement filed 02 April 2001) in view of Choo et al. (1994a) (Proc, Natl. Acad. Sci. USA Vol. 91, pages 11163-11167, reference DD in the information disclosure statement filed 02 April 2001).

The claims are drawn to a method of designing a zinc finger protein comprising three zinc fingers that binds to a target site by using a database that comprises a plurality of zinc finger protein sequences in which the zinc finger domains are correlated with their respective DNA binding target. In some embodiments the zinc finger proteins in the database are precharacterized, the designed zinc finger protein is synthesized, or subsets of proteins from the database are determined. In some embodiments the claims are drawn to computers or computer programs that execute the method, or a computer mediated method.

Choo et al. (1994b) shows a method of designing a zinc finger protein that binds to a BCR-ABL recombined oncogene target site. Choo et al. (1994b) shows on pages 642-643 that each triplet of the intended binding site (shown in figure 1) was used to screen a randomized zinc finger library made by the method of Choo et al. (1994a). Selected zinc fingers that bound a desired triplet were combined into a set of three finger zinc finger proteins shown in figure 2 and further screened to select the zinc finger protein that bound the intended binding site. One zinc finger designated 1A-2A-3B was selected for expression. The expressed zinc finger protein bound the intended binding site as shown in figure 3. The zinc finger proteins selected from the randomized library represent subsets of the randomized library. Choo et al. (1994b) does not

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explicitly show that the randomized library of zinc finger proteins consists of three finger zinc finger proteins, and further does not show the extent of precharacterization of the zinc finger proteins in the randomized zinc finger library or a database of the randomized zinc finger library. Choo et al. (1994b) does not show a computer-mediated method or computers or programs that execute the method.

Choo et al. (1994a) shows on pages 11163-11164 a phage library comprising zinc finger genes in which the middle of three fingers is randomized. Choo et al. (1994a) shows on pages 11164-11166 that the library can be used to screen for members that bind the middle triplet of choice of a polynucleotide binding target. Choo et al. (1994a) shows in figure 1 the three fingers and three alternative polynucleotide binding targets. Choo et al. (1994a) shows in figure 2 a database of selected and characterized library members. Choo et al. (1994a) discusses the amino acid sequence and putative secondary structures of the binding region of the selected library members.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to precharacterize the selected random library members of Choo et al. (1994b) to any desired extent to aid in further analysis of selected library members because Choo et al. (1994a) shows such analysis in figure 2 and pages 11164-11167. It would have been further obvious to record such characterizations in a database as shown in Choo et al. (1994a) figure 2. It would have been further obvious to automate the generation and use of their database by use of computers and appropriate programs because it is obvious to one of ordinary skill in the art to automate a process (see MPEP 2144.04).

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Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

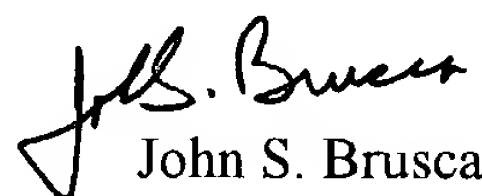
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is (571) 272-0714. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John S. Brusca

Primary Examiner

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jsb